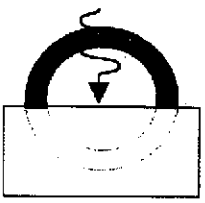
DEC 2 3 2009



SIMUPLAN S.L.
Miguel Hernandez 25
La Eliana
46183 Valencia
Spain
Phone: (+34) 96-274-3827
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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by section 807.92(c)

Submitter of 510(k):

Company name:	**SIMUPLAN S. L.**
Registration number:	3004147829
Address:	Miguel Hernandez 25 La Eliana 46183 Valencia Spain
Phone:	(+34) 96-274-3827
Fax:	(+34) 96-272-5132
Contact Person:	Conrado Pla Ph.D.

Modified Device Name:

Trade/Proprietary Name:	SIMUPLAN Treatment Planning System
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical, Accessory
Classification	21 CFR 892.5050 Class II Product Code: MUJ

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
SIMUPLAN	SIMUPLAN Treatment Planning System, v 7.5	K030821

Description:

The SIMUPLAN Treatment Planning System is computer based software that runs on a MacIntosh platform. The planning system is comprised of 2 main components; external beam and brachytherapy.

The modified device, SIMUPLAN Treatment Planning System version 8.4 software release, is a brachytherapy module update only. The external beam software is not included in this release.

With the brachytherapy module, the patients' image sets (i.e. CT, MR, US or x-ray films) are imported into the system by various methods: DICOM, disk, video, etc. From this data the patients' anatomical structures and tumor site is contoured in order to generate a 3D patient model, or x-ray films are used for 2D reconstruction of the implant area. Following the import of images, the next steps in the process will be to define the treatment machine, reconstruct implant applicators or define template and seed location. From this information the user will select the appropriate source (afterloading or seed) to be used for the planning session. Based on the target volume or reconstructed implant, treatment source and prescription dose the treatment plan will be calculated and a dose distribution will be displayed. This treatment plan can be modified by the physician prior to final output and patient treatment. The physician approved treatment plan is then printed out, machine data generated (for remote afterloading) and a hard copy of the isodose distribution is prepared for the patients' permanent record. The patient data is then saved under a unique file name in the patient database. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Intended Use:

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Summary of Technological Considerations:

The SIMUPLAN Treatment Planning System version 8.4 is substantially equivalent to the cleared predicate device, SIMUPLAN Treatment Planning System version 7.5 , (#K030821).

Conrado Pla

Name: Conrado Pla, Ph.D.

Title: President

SIMUPLAN S.L.

October 23, 2009

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2009

Simuplan S.L.
% Ms. Lu Anne Johnson
President
CAPAMED, Inc.
1917 29 ¾ Ave
RICE LAKE WI 54868

Re: K093391
Trade/Device Name: Simuplan Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: December 2, 2009
Received: December 8, 2009

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K093391**

Device Name: **SIMUPLAN Treatment Planning System**

Indications for Use:

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient; all information must be confirmed by the physician prior to treatment.

Prescription Use **X** AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093391